SUBSTITUTE FORM PTO-1449 (MODIFIED)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE

STATEMENT BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO.: 3100-0003

SERIAL NO

APPLICANT:

Jenny LOUIE-HELM et al.

GROUP:

(37 CFR 1.98(b))

FILING DATE:

Concurrently herewith

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			U.S. PA	TENT DOCUMENTS			
EXAMINER INITIALS	CITE NO.	PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
BF	AA	3,960,150	6/1/76	Hussain et al.			
On C	AB	4,695,467	9/22/87	Uemura et al.			
35	AC	5,002,772	3/26/91	Curatolo et al.			
BF	AD	5,007,790	4/16/91	Shell			
BF	AE	5,425,950	6/20/95	Dandiker et al.			
AC.	AF	5,582,837	10/10/96	Shell			
66	AG	5,635,210	6/3/97	Allen, Jr. et al.	TI F TO THE		
BF	АН	5,738,874	4/14/98	Conte et al.			
BF	AI	5,783,212	7/21/98	Fassihi et al.			
BC	AJ	5,827,984	10/27/98	Sinnreich et al.			
MC	AK	5,840,332	11/24/98	Lerner et al.		. /	
BC	AL	5,861,173	1/19/99	Nishioka et al.			
bo	AM	5,891,474	4/6/99	Busetti et al.			
80	AN	5,945,125	8/31/99	Kim			
BE	AO	5,972,389	10/26/99	Shell et al.		/	
m	AP	6,027,748	2/22/00	Conte et al.			
h	AQ	6,066,337	5/23/00	Allen et al.			
GNF	AR	6,093,420	7/25/00	Baichwal			
36	AS	6,120,803	9/19/00	Wong et al.			
X	AT	6,174,497	1/16/01	Roinestad et al.			8/21/97

EXAMINER SIGNATURE: Blossing Fubara

DATE CONSIDERED:

8/8/03

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SUBSTITUTE	<b>FORM</b>	PTO-1449
(MODIFIED)		

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	U.S. PATENT DOCUMENTS							
EXAMINER INITIALS	CITE NO.	PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
BF	AU	6,177,104	1/23/01	Allen et al.			7/6/98	
BG	AV	6,187,337	2/13/01	Allen et al.			7/6/98	
K	AW	6,221,395	4/24/01	Maggi et al.			9/1/88	
		OTHER DOCU	MENT — N	ONPATENT LITERATU	RE DOCUME	NT		
EXAMINER INITIALS								
AX Katori et al. (1995), "Estimation of Agitation Intensity in the GI Tract in Humans and Dogs Based on in Vitro/in Vivo Correlation," Pharmaceutical Research 12(2):237-243.								

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	Complete if Known				
Substitute for form 1449A/PTO	Application Number	10/014,750			
O PREFORMATION DISCLOSURE	Filing Date	October 25, 2001			
	First Named Inventor	Jenny LOUIE-HELM et al.			
STATEMENT BY APPLICANT	Art Unit	1615			
(use as many sheets as necessary)	Examiner Name	Blessing M. Fubara			
Sheet 1 of 3	Attorney Docket Number	3100-0003			

CERTIFICATION			U.S. PATENT I	DOCUMENTS			
Examiner Initials*	Cite No.	Document No.	Issue Date or Publication Date	Name of Patentee or Applicant of Cited Document	Class	Subclass	Filing Date if Appropriate
*	ΑY	4,434,153	2/28/84	Urquhart et al.			Α.
	AZ	4,690,824	9/1/87	Powell et al.	/	1	160
	BA	4,748,023	5/31/88	Tamás et al.		A	
	BB	4,786,503	11/22/88	Edgren et al.	/	(C)	PA
	BC	4,839,177	6/13/89	Colombo et al.	,	7/	200
	BD	4,851,232	7/25/89	Urquhart et al.		<b>├</b> ─~	1/2 - 20
	BE	4,865,849	9/12/89	Conte et al.			(\$\dag{\alpha})
	BF	5,064,656	11/12/91	Gergely et al.			1600/2
	BG	5,085,865	2/4/92	Nayak/			00/2
	ВН	5,213,808	5/25/93	Bar-Shalom et al.			
	BI	5,232,704	8/3/93	Franz et al.	İ		
	BJ	5,393,765	2/28/95	Jńfeld et al.			
	BK	5,422,123	6/6/95	/ Conte et al.			
<del></del>	BL	5,458,887	10/17/95	/ Chen et al.			
· · · · · · · · · · · · · · · · · · ·	BM	5,458,888	10/17/95	Chen			
	BN	5,464,633	11/7/95	Conte et al.			
	ВО	5,472,708	12/5/95	Chen			
	BP	5,487,901	1/30/96/	Conte et al.			
-	BQ	5,508,040	4/16/96	Chen			
	BR	5,549,913	8/27/96	Colombo et al.	T 0		Y
	BS	5,609,590	/3/11/97	Herbig et al.			
	BT	5,626,874	/ 5/6/97	Conte et al.			
	BU	5,650,169	7/22/97	Conte et al.			
	BV	5,651,985	7/29/97	Penners et al.			
	BW	5,681,583	10/28/97	Conte et al.			
	BX	5,688,776/	11/18/97	Bauer et al.			7
	BY	5,736,1,59	4/7/98	Chen et al.			27
	BZ	5,780,057	7/14/98	Conte et al.			
	CA	5,811,126	9/22/98	Krishnamurthy			
	CB	,5,837,379	11/17/98	Chen et al.			
-111	CC	5,840,329	11/24/98	Bai			
	CD	5,897,874	4/27/99	Stevens et al.			
	CE	5,916,595	6/29/99	Chen et al.			
	CF/	6,033,685	3/7/00	Qiu et al.			
	ÇĞ	6,207,197	3/27/01	Illum et al.			
	/с́н	6,261,601	7/17/01	Talwar et al.			•
	CI	6,340,475	01/22/02	Shell et al.	<b> </b>		
	CJ	6,368,628	4/9/02	Seth		<del> </del>	5/26/00
<del>/</del>	CK	6,451,808	9/17/02	Cowles			10/17/00
<del>/</del>				Berner et al.			6/20/00
/	CL	6,488,962	12/3/02	Berner et al.			6/20/00

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Substitute	for form 144	9A/PTO			Application Number	10/014,750	0	84
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					First Named Inventor	Jenny LOUIE-HELM	1 et al.	9
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	CM	200	1/0018070	8/30/01	Shell et al.			
<b>—</b>	CN	Serial N	09/425 491		Shell et al		10/2	2/99

CM	2001/0018070	8/30/01	Shell et al.			
CN	Serial No. 09/425,491		Shell et al	1		10/22/99
 CO	Serial No. 10/029,134		Gusler et al.		/	10/25/01
 CP	Serial No. 10/045,823		Shell et al.			11/6/01
CQ	Serial No. 10/066,146		Lim et al.			2/1/02
CR	Serial No. 10/152,914		Fara et al.			5/20/02
CS	Serial No. 10/280,309		Berner et al.			10/25/02
CT	Serial No. 10/280,852		Devane et al.		ă.	10/25/02

		FOREIGN P	ATENT DOCUM	MENTS /			
Examiner Initials*	Cite No.	Foreign Patent Document No.	Publication Date	Country	Class	Subclass	T
	CU	EP 0598309 B1	1/28/98	Europe			
	CV	EP 0795324 A2	9/17/97 /	Europe			
	CW	GB 1330829	9/19/73/	United Kingdom			•
	CX	WO 96/32097 A1	10/1,7/96	PCT			
	CY	WO 98/55107 A1	1,2/10/98	PCT			
	CZ	WO 00/23045 A1	/4/27/00	PCT			
	DA	WO 00/38650 A1	7/6/00	PCT			
	DB	WO 01/32217 A3	5/10/01	PCT			
	DC	WO 01/56544 A3	8/9/01	PCT			
	DD	WO 01/97783 A1	12/27/01	PCT			
-	DE	WO 02/083687 A1/	10/24/02	PCT			

		OTHER DOCUMENTS — NONPATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), Title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Т
	DF	Abrahamsson, et al. (1993), "Absorption, Gastrointestinal Transit, and Tablet Erosion of Felodipine Extended-Release (ER) Tablets," <i>Pharmaceutical Research</i> 10(5):709-714.	
	DG	Apicella et al./(1993), "Poly(ethylene oxide) (PEO) and Different Molecular Weight PEO Blends Monolithic, Devices for Drug Release," <i>Biomaterials</i> 14(2):83-90.	
-	DH	Baumgarther et al. (2000), "Optimisation of Floating Matrix Tablets and Evaluation of Their Gastric Residence Time," <i>International Journal of Pharmaceutics</i> 195:125-135.	
	DI	Bettini et al. (1994), "Swelling and Drug Release in Hydrogel Matrices: Polymer Viscosity and Matrix Porosity Effects," European Journal of Pharmaceutical Sciences 2:213-219.	
	DJ	Chen et al. (2000), "Gastric Retention Properties of Superporous Hydrogel Composites," <i>Journal of Controlled Release</i> 64:39-51.	
	DK	Columbo et al. (1990), "Drug Release Modulation by Physical Restrictions of Matrix Swelling," International Journal of Pharmaceutics 63:43-48.	
	DL	Davis et al. (1986), "The Effect of Density on the Gastric Emptying of Single- and Multiple-Unit Dosage Forms," <i>Pharmaceutical Research</i> 3(4):208-213.	
/	<sup>'</sup> DM	Deshpande et al. (1997), "Development of a Novel Controlled-Release System for Gastric Retention," <i>Pharmaceutical Research</i> 14(6):815-819.	
	DN	Ford et al. (1987), "Importance of Drug Type, Tablet Shape and Added Diluents on Drug Release Kinetics from Hydroxypropylmethylcellulose Matrix Tablets," <i>International Journal of Pharmaceutics</i> 40:223-234.	

Examiner Signature Date Considered

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute for form 1449A/PTO	Application Number	10/014,750	2
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	First Named Inventor	Jenny LOUIE-HELM et al	8
STATEMENT BY APPLICANT	Art Unit	1615	
(use as many sheets as necessary)	Examiner Name	Blessing M. Fubara	
Sheet 3 of 3	Attorney Docket Number	3100-0003	3

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MADELLADA		OTHER DOCUMENTS — NONPATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), Title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Т
	DO	Gao et al. (1996), "Swelling of Hydroxypropyl Methylcellulose Matrix Tablets. 2. Mechanistic Study of	
		the Influence of Formulation Variables on Matrix Performance and Drug Release," Journal of	
		Pharmaceutical Sciences <u>85</u> (7):732-740.	
	DP	Hwang et al. (1998), "Gastric Retentive Drug-Delivery Systems," Critical Reviews in Therapeutic Drug Carrier Systems 15(3):243-284.	
	DQ	Ju et al. (1995), "Drug Release from Hydrophillic Matrices. 1. New Scaling Laws for Predicting Polymer	
		and Drug Release Based on the Polymer Disentanglement Concentration and the Diffusion Layer,"	
		Journal of Pharmaceutical Sciences 84(12):1455-1463.	
	DR	Ju et al. (1995), " Drug Release from Hydrophillic Matrices. 2. A Mathematical Model Based on the	:
		Polymer Disentanglement Concentration and the Diffusion Layer," Journal of Pharmaceutical Sciences	
		84(12):1464-1477.	
	DS	Kaniwa et al. (1983), "The Bioavailability of Flufenamic Acid and Its Dissolution Rate from Capsules,"	
		International Journal of Clinical Pharmacology, Therapy and Toxicology 21(2):56-63.	
	DT	Kim (1995), "Drug Release from Compressed/Hydrophilic POLYOX-WSR Tablets," Journal of	
,		Pharmaceutical Sciences 84(3):303-306.	
	DU	Lapidus et al. (1966), "Some Factors Affecting the Release of a Water-Soluble Drug from a Compressed	
		Hydrophilic Matrix," Journal of Pharmaceutical Sciences 55(8):840-843.	
	DV	Lapidus et al. (1968), "Drug Release from Compressed Hydrophilic Matrices," Journal of Pharmaceutical	
		Sciences <u>57(8)1292-1301.</u>	
	DW	Maggi et al. (2000), "High Molecular Weight Polyethylene Oxides (PEOs) as an Alternative to HPMC in	
		Controlled Release Dosage Forms," International Journal of Pharmaceutics 195:229-238.	
	DX	Maggi et al. (2000), "Highly Swellable Multi-Layer Tablets to Prolong the Residence Time of the Delivery	
		in the Stomach," Journal of Controlled Release 64:269-347.	
	DY	Oth et al. (1992), "The Bilayer Floating Capsule: A Stomach-Directed Drug Delivery System for	
		Misoprostol," Pharmaceutical Research 9(3):298-302.	
	DZ	Rao et al. (1988), "Swelling Controlled-Release Systems: Recent Developments and Applications,"	
		International Journal of Pharmaceutics <u>48</u> :1-13.	
	ΕA	Reynolds et al. (1998), "Polymer Erosion and Drug Release Characterization of Hydroxypropyl	
		Methylcellulose Matrices" Journal of Pharmaceutical Sciences 87(9):1115-1123.	
	EB	Shameem et al. (1995), "Oral Solid Controlled Release Dosage Forms: Role of GI-Mechanical	
	,	Destructive Forces and Colonic Release in Drug Absorption Under Fasted and Fed Conditions in	
		Humans," Pharmaceutical Research 12(7):1049-1054.	
	ΈC	Siepmann et al. (1999) "HPMC Matrices for Controlled Drug Delivery: A New Model Combining	
		Diffusion, Swelling, and Dissolution Mechanisms and Predicting the Release Kinetics" Pharmaceutical	
/		Research <u>16</u> (11):1748-1756.	
	ED	Yang et al. (1996), "Zero-Order Release Kinetics from a Self-Correcting Floatable Asymmetric	
		Configuration Drug Delivery System," Journal of Pharmaceutical Sciences 85(2):170-173.	

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Signature	Considered	

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